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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,096	12/30/2003	Doddabele L. Madhavi	BIO 2-013	6934

7590 06/29/2005
Jerry K. Mueller, Jr.
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7700 Rivers Edge Drive
Columbus, OH 43235

EXAMINER

FEDOWITZ, MATTHEW L

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,096	MADHAVI ET AL.	
	Examiner	Art Unit	
	Matthew L. Fedowitz	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,3,7,8,13,14 and 20-22 is/are allowed.
- 6) ☒ Claim(s) 1,4-6,9-12,15,16 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The finality of the office action dated April 21, 2005 is withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 5, 6, 9, 10, 11, 12, 15, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. and Gattuso et al.

I. Claims 1, 4 and 5 are directed to a water-dispersible, freeze-dried bioavailable coenzyme Q-10 and one or more of α , β or γ -cyclodextrin complex that can be formulated into a topical or sublingual formulation for oral ingestion.

The teachings of Iijima et al. are discussed in the office actions dated October 29, 2004 and April 21, 2005. Iijima does not teach the underivatized α , β or γ -cyclodextrin in the complex. However, Gattuso et al. state that the three most popular cyclodextrins are α , β and γ -cyclodextrin and the best-known derivative is dimethyl- β -cyclodextrin (see p. 1955 first column bottom of the page).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings above to obtain the compositions as claimed in the instant application. Obviousness based on similarity of structure and functions entails motivation to make the claimed compositions in expectation that compounds similar in structure will have similar properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compositions in searching for complexing agents for coenzyme Q10.

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II. Claims 6 and 9 are directed to a method for making a water dispersible complex of coenzyme Q10 and cyclodextrin. Claims 10, 11, 12, 15, 16 and 19 are directed to a method for administering to an animal a bioavailable coenzyme Q10/ cyclodextrin complex.

The methods of making and administering dimethyl- β -cyclodextrin that are taught by Iijima et al. are discussed in the office actions dated October 29, 2004 and April 21, 2005. Iijima does not teach methods using the underivatized α , β or γ -cyclodextrin in the complex. Gattuso et al. though teaches the best-known derivatized and underivatized cyclodextrins that one of ordinary skill in the art would substitute for the dimethyl- β -cyclodextrin in Iijima et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings above to obtain the methods as claimed in the instant application. Obviousness based on similarity of structure and function entails motivation to claim the methods as the applicant has in expectation that compounds similar in structure will have similar properties. Therefore, one of ordinary skill in the art would be motivated to substitute α , β or γ -cyclodextrin for dimethyl - β -cyclodextrin in searching for complexing agents with coenzyme Q10 for use in methods of making and administering such compounds.

Allowable Subject Matter

Claims 2, 3, 7, 8, 13, 14, 20, 21, and 22 would be allowable if rewritten in independent form with all the limitations pertaining thereto. The prior art does not teach or fairly suggest the subject matter as claimed by the applicant. As relating to claims 2, 3, 7, 8, 13, 14 and dependent claim 20, the prior art does not disclose any molar ratios for use in methods of making or

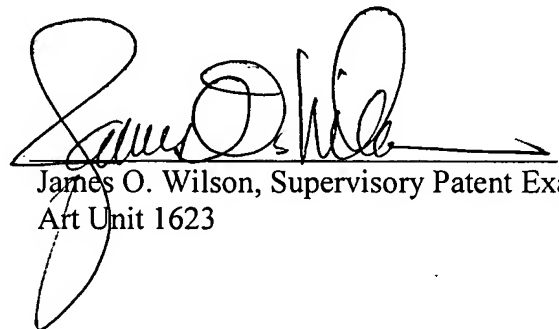
administering. As relating to claim 21 and 22, the prior art does not teach a step where coenzyme Q10 is added to cyclodextrin at room temperature followed by refrigeration.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105. If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew L. Fedowitz, Pharm.D., Esq.

A handwritten signature in black ink, appearing to read 'James O. Wilson', with a long horizontal stroke extending to the right.

James O. Wilson, Supervisory Patent Examiner
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